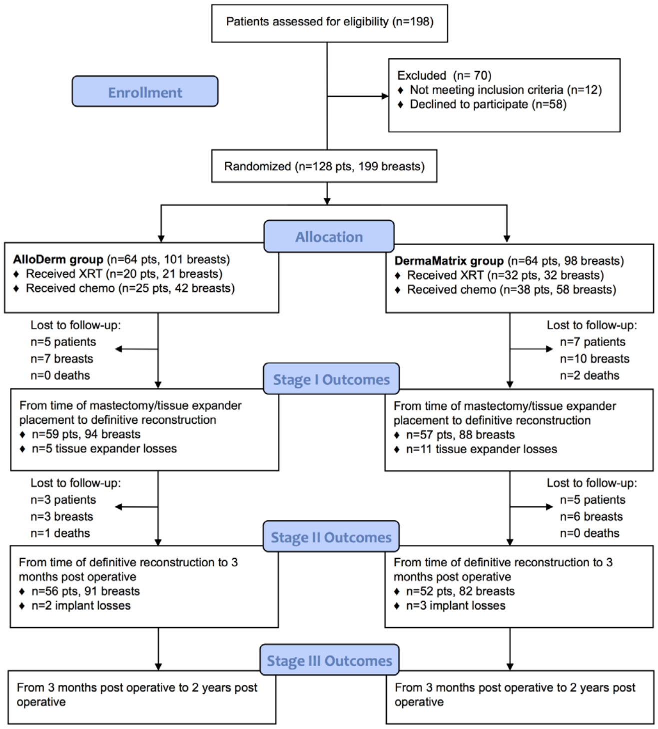
Patients assessed for eligibility (n=198)
Enrollment
Excluded (n= 70)
♦ Not meeting inclusion criteria (n=12)
♦ Declined to participate (n=58)
Randomized (n=128 pts, 199 breasts)
Allocation
AlloDerm group (n=64 pts, 101 breasts)
♦ Received XRT (n=20 pts, 21 breasts)
♦ Received chemo (n=25 pts, 42 breasts)
DermaMatrix group (n=64 pts, 98 breasts)
♦ Received XRT (n=32 pts, 32 breasts)
♦ Received chemo (n=38 pts, 58 breasts)
Lost to follow-up:
n=5 patients
n=7 breasts
n=0 deaths
Lost to follow-up:
n=7 patients
n=10 breasts
n=2 deaths
Stage I Outcomes
From time of mastectomy/tissue expander placement to definitive reconstruction
♦ n=59 pts, 94 breasts
♦ n=5 tissue expander losses
From time of mastectomy/tissue expander placement to definitive reconstruction
♦ n=57 pts, 88 breasts
♦ n=11 tissue expander losses
Lost to follow-up:
n=3 patients
n=3 breasts
n=1 deaths
Lost to follow-up:
n=5 patients
n=6 breasts
n=0 deaths
Stage II Outcomes
From time of definitive reconstruction to 3 months post operative
♦ n=56 pts, 91 breasts
♦ n=2 implant losses
From time of definitive reconstruction to 3 months post operative
♦ n=52 pts, 82 breasts
♦ n=3 implant losses
Stage III Outcomes
From 3 months post operative to 2 years post operative
From 3 months post operative to 2 years post operative

Figure 1. BREASTrial flowchart and outcome stages. Flowchart adapted from Consort 2010. Pts: patients, XRT: radiation therapy, chemo: chemotherapy.

Table 1. Stage II Outcomes and Complications.

	AlloDerm	DermaMatrix	P Value
Overall complications	11.0 %	12.2 %	0.4
Infection	3.3 %	6.1 %	0.2
Hematoma	1.1 %	0 %	0.2
Seroma	0 %	0 %	na
Skin necrosis	2.2 %	2.4 %	0.5
Implant loss	2.2 %	2.4 %	0.5

CONCLUSIONS: The BREASTrial is the largest prospective randomized trial to date in ADM breast reconstruction. Results from Stage II demonstrate the need for careful patient selection in ADM breast reconstruction. Regression analysis indicated that obesity was associated with complications which raises concern for ADM use in this population. The trial also revealed that autologous reconstruction after ADM-assisted tissue expansion does not lead to more complications than implant-based reconstruction. Results from the BREASTrial will assist plastic surgeons in making evidence-based decisions regarding ADM-assisted breast reconstruction.

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Three Years Experience with Absorbable Mesh in Single-Stage Breast Reconstruction: A Cost-Effective Alternative

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PURPOSE: The current state of healthcare in the United States mandates elimination of unnecessary costs while increasing efficiency in patient care. Traditional implant-based breast reconstruction encompasses multiple stages, and the use of acellular dermal matrix (ADM), both of which significantly increase the cost of care. Immediate single-stage direct-to-implant (DTI) breast reconstruction is an efficient reconstructive method. The senior author (WGA) has used absorbable knitted mesh (Vicryl™ - polyglactin 910) as an inferior pole sling in DTI breast reconstruction since 2011. We report 3 years of outcomes and cost savings data using this material.

METHODS: All patients who underwent DTI since we started using mesh in 2011 were entered retrospectively into our database. Patients included in the analysis are from 2011 through December 2014. Information captured includes demographics, intra-operative details, post-operative data (including complications), cancer-related therapies, and comorbidities. Stata/IC 13.1 was used for statistical analysis.

RESULTS: DTI was performed on 155 patients (56 unilateral, 99 bilateral; 254 breasts). A representative patient is shown in Figure 1 (pre-op) and Figure 2 (post-op). Mean age was 51.9 years (range 24-79.8 years). Mean post-op time was 25.2 months. Prophylactic mastectomy rate was 39.4%. Percentage of irradiated breasts (pre- or post-operative) was 28.4%. Infection rate was 1.6% (n = 4 breasts). Five implants (2%) were exposed (3 were salvaged). Seven implants (2.8%) were removed. Ten breasts (3.9%) had capsular contracture (5 had additional surgery: 2 flaps, 3 capsulotomy/capsulectomy with implant exchange). Capsular contracture was significantly greater in irradiated breasts (11.1% vs 1.1%, p = 0.0002). Material cost savings using mesh over ADM was greater than $585,000.

Figure 1. Pre-operative.

Figure 2. Post-operative – 31 months after bilateral DTI with implants and absorbable mesh.

CONCLUSION: We have 3 years of experience using absorbable knitted mesh for DTI. We continue to maintain a low complication rate and a high level of patient and surgeon satisfaction with aesthetic outcomes. In addition, we have achieved substantial efficiency and cost reduction in comparison to the use of ADM.

Positive Impact of Meshing Autogenous Dermal Matrix (ADM) on Pain, Length of Stay and Length of Time Required for Post-Operative Drains in Tissue Expander Based Breast Reconstruction

Sarah E. Hagarty, BS, MD; Lawrence Yen, BS; Christopher Fosco, MD; Manorama Khare, PhD

INTRODUCTION: Seroma rates when ADM is used in tissue expander based breast reconstruction have been of concern.[1-3] The impact of fenestrating and perforating various ADMs has been studied. [4,5] We tested a simple and reproducible method to mesh ADM. We hypothesized this would have a positive impact on postoperative drainage.

MATERIALS AND METHODS: Thin Alloderm® was meshed with either a Brennan® or Zimmer® device for expander based reconstruction in a single surgeon practice over 2 years. This cohort was compared to a previous cohort, with unmeshed ADM. Drain times, length of stay (LOS), parenteral narcotic usage (mg morphine), and complication rates were compared: 36 meshed versus 116 unmeshed breasts, 19 and 84 patients respectively. T-test and Levine's test for equality of variances were employed. Outcomes in the two groups were analyzed, controlling for variables: diabetes, hypertension, smoking status, BMI, expander size, fill volume, and prior radiation therapy. Follow up was 2 and 8 years respectively.

RESULTS: In bivariate analysis, mean time for drain removal was 18(+/-5) days in meshed, versus 29(+/-19) days unmeshed, ($p < 0.001$). Parenteral narcotic use decreased in the meshed group, (6.8 versus 29 mg morphine, $p < 0.002$), with no difference in intraoperative fill volumes. LOS decreased from 1.8 to 1.1 days, ($p<0.002$). Complication rates were not significantly different. Minor complications trended lower (13.9 % meshed versus 27.4%, $p=0.09$). Major complication rates (8.3% meshed versus 4.8%) were not significantly different, ($p=0.42$). Prior radiation was higher in the meshed group (21% versus 2%). The major complication rate trended lower (0% versus 4.8%), when discounting prior radiation.

CONCLUSIONS: We present a novel, and easily reproducible technique to manipulate ADM, resulting in a significant decrease in time for drains, use of parenteral narcotics, and length of stay. Further statistical analysis is pending with a larger cohort to determine if differences in complication rates will reach statistical significance.

REFERENCES:

1. Antony AK, McCarthy CM, Cordeiro PG, et al. Acellular Human Dermis Implantation in 153 Immediate Two-Stage Tissue Expander Breast Reconstructions: Determining the Incidence and Significant Predictors of Complications. *Plast Reconstr Surg.* 2010 Jun;125(6):1606-14.